

REMARKS

Status of the Claims

Claims 95-149 were pending. Claims 105-112, 114-117, 122, 123, 132, 133, 142 and 143 were asserted by the Office Action mailed 1/12/06 to be withdrawn as drawn to non-elected species. However, as discussed below, Applicants respectfully submit that the species election dated 1/20/2004 was mis-interpreted and assert that the presently pending claims are consistent with the actual species election, a copy of which is attached herewith for convenience, along with a copy of the corresponding restriction requirement. Claims 101-104, 109, 111-112, 114, 116-125 and 128-149 are canceled herein. Claims 95-100, 105, 107, 108, 113, 115 and 126-127 are amended herein to further clarify the claimed subject matter. Support for the amendments is discussed below in the section on written description support. Applicants submit that no new subject matter is added by amendment. Claims 95-100, 105-108, 110, 113, 115 and 126-127 are presently pending.

Species Election of 1/20/2004

Attached hereto are copies of the restriction requirement mailed 12/18/2003 and response to restriction requirement, dated 1/20/2004. The Action (mailed 1/12/2006) at Paragraph 3 asserts that, "Applicant's election of the species antibody of SEQ ID No 2 and 4 in the reply filed on 1/20/2004 is acknowledged." Applicants respectfully traverse.

The restriction requirement mailed 12/18/03, stated that, "This application contains claims directed to the following patentably distinct species of the claimed invention. The various different nucleic acids encoding a particular antibody. For example, the nucleic acid encoding the antibody of SEQ ID NO:2 and 4, or the nucleic acid encoding the antibody of claim 111, etc). These are different antibodies with different sequences. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable."

By use of the phrase, "for example," the restriction requirement made clear that the species to be elected were not limited to "the antibody of SEQ ID NO:2 and 4," or "the antibody of claim 111." Rather, the choice of the disclosed species was left to the Applicants to select.

In the response dated 1/20/04, “Applicant hereby provisionally elects claims directed to a polynucleotide sequence encoding an antibody that contains one or more CDRs from SEQ ID NOS:2 and/or 4 (amino acid sequences of the variable light and heavy chain murine LL2 monoclonal antibody) or components of these antibodies, such as individual CDRs, light chain variable regions or heavy chain variable regions containing these CDRs.”

Thus, the species elected was the polynucleotide encoding an antibody or fragment thereof containing one or more CDRs from SEQ ID NO:2 and/or SEQ ID NO:4. Applicants respectfully submit that all pending claims read on the elected species. Further, Applicants submit that the species was a proper species for election. All embodiments of the elected species share a common structural feature – they contain one or more CDRs selected from SEQ ID NO:2 and/or SEQ ID NO:4. Further, this common structural feature is related to the function of the encoded antibody or fragments thereof – that of binding to the same antigen as the murine LL2 antibody from which the CDR sequences were obtained. It is well known in the art that antigen-binding specificity is determined by the CDR sequences of antibodies. The Action explicitly recognized this fact, stating that, “The claims reading on CDRs derived from the elected species have been included as part of the elected species.” All presently pending claims read on CDRs derived from SEQ ID NO:2 and/or SEQ ID NO:4.

Non-statutory Double Patenting Rejection

The claims were rejected on the ground of non-statutory obviousness-type double patenting over claims 25-27 of U.S. Patent No. 6,187,287. Applicants respectfully traverse. Claims 25-27 of U.S. Patent 6,187,287 are drawn to DNA sequences or vectors encoding chimeric LL2 antibodies or fragments thereof (cLL2), “wherein said cLL2 mAb retains substantially the B-lymphoma cell and leukemia cell targeting and cell internalization characteristics of said mLL2 mAb.” Applicants respectfully submit that claims 25-27 of U.S. Patent 6,187,287 are patentably distinct from the instant claims, which do not recite the limitations cited in the preceding sentence.

Rejection of Claims Under 35 USC 112, 1st Paragraph

The claims were rejected under 35 USC 112, 1st paragraph for failure to comply with the written description requirement. The Action asserts that, “There is no support in the specification as

originally filed for the nucleic acids of claims 95-100.” Applicants respectfully traverse the assertion.

Concerning claims 95-100, the claims as amended concern isolated polynucleotides encoding humanized or chimeric antibody fragments comprising the light chain CDR1, CDR2 and/or CDR3 or the heavy chain CDR1, CDR2 and/or CDR3. Applicants submit there is ample written description support for those claims.

First, the Action at Paragraph 15 states that, “All of the instant polynucleotide claims are considered ‘open’ and therefore encompass the nucleic acids encoding the chimeric LL2 antibody.” This is consistent with the use of “comprising” in the instant claims.

Applicants submit that Figures 5A and 5B disclose isolated polynucleotides encoding humanized or chimeric antibody fragments comprising CDR1, CDR2 and/or CDR3 of the LL2 light chain and/or CDR1, CDR2 and/or CDR3 of the LL2 heavy chain. The skilled artisan, viewing Figure 5, would clearly conclude that Applicants were in possession of isolated polynucleotides encoding humanized or chimeric antibody fragments comprising CDR1, CDR2 and/or CDR3 of the LL2 light chain and/or CDR1, CDR2 or CDR3 of the LL2 heavy chain as of the priority date of the instant application.

Further, Figure 6 and Example 3 of the instant application show that the humanized VH sequence was produced in the form of two polynucleotides – identified as “oligo A” and “oligo B.” Example 3 discloses that “oligo A” extended from nucleotides 24 to 172 of the complementary hLL2 VH domain, while “oligo B” extended from nucleotides 180 to 320 of the hLL2 VH. Examination of FIG 5B shows that oligo A encoded the amino acid sequence comprising CDR1 and part of CDR2 of the heavy chain hLL2, while oligo B encoded the amino acid sequence comprising CDR3 and part of CDR2 of the heavy chain hLL2. The Specification at page 11, line 15 to page 12, line 17, page 26, lines 26-28, and page 27, lines 1-24 discloses that the nucleic acid encoding the light chain variable sequence of hLL2 was also synthesized in 2 segments, the first encoding CDR1 and part of CDR2 and the second encoding CDR3. Such polynucleotides are of use, for example, to construct an intact humanized or chimeric LL2 antibody or a fragment thereof with the same binding and internalization characteristics of the mouse LL2 antibody. The cited passages and

oligos A and B explicitly disclose “nucleic acids encoding variable heavy chain and or variable light chains wherein said nucleic acids encode less than all of the CDRs found in the LL2 heavy and or light chain variable chain regions,” for which the Action at Paragraph 12 asserts a lack of written description support.

The skilled artisan, reading the Specification as cited above, would conclude that Applicants were in possession of polynucleotides encoding humanized or chimeric antibody fragments comprising CDR1, CDR2 and/or CDR3 of the light and/or heavy chains of LL2 as of the priority date of the instant application.

Claim 113 also finds support in the Specification in Figures 5A and 5B and in Examples 3 and 4, which clearly describe the construction of polynucleotides and vectors encoding humanized and chimeric VH and VL sequences comprising CDR1, CDR2 and CDR3 of the light and heavy chains of LL2. Thus, the skilled artisan reading the specification would conclude that Applicants were in possession of the subject matter of Claim 113 as of the instant priority date.

Applicants further submit that there is support in the Specification for amended claims 105-110, which depend from claim 113 and therefore concern isolated polynucleotides encoding humanized or chimeric antibodies or fragments thereof, comprising CDR1, CDR2 and CDR3 of the light and heavy chain variable sequences of LL2. As acknowledged in the Action at Paragraph 12, “The specification discloses chimeric LL2 antibody or humanized LL2 antibody wherein said nucleic acids encode all of the CDRs derived [from] the murine LL2 antibody and contain human FR regions (humanized) or the FR regions of the murine LL2 antibody.” Thus, even the Action asserts that claim 113 is fully supported by the Specification and that written description support also exists for dependent Claims 105 and 110.

With respect to the FR substitutions of claims 106-108, there is disclosure throughout the Specification in support, including at least Example 1, which discloses a glutamine for valine substitution at amino acid position 5 and Example 8, which discloses substitution of glutamine for asparagine at residue 18 in FR1.

The subject matter of amended Claim 107 is supported in the Specification at least at page 10, line 17 to page 11, line 13. Page 2, lines 22-34 of the Specification identifies CD22 as the LL2-

binding antigen on B-cells. Page 5, lines 2-19 of the Specification support that the cLL2 and hLL2 mAbs retain the antigenic specificity of the mouse LL2 antibody. There is ample support in the Specification that the CDRs incorporated into hLL2 and cLL2 were derived from the murine LL2 mAb.

Expression vectors comprising the claimed polynucleotides (Claim 126) are disclosed in the Specification at least at Example 3 and Figure 3. The Action at Paragraph 12 notes that, “The specification discloses the use of ‘mammalian expression cells’” (Claim 127).

Priority to Parent Applications

Paragraph 13 of the Action asserts that the instant application is not entitled to priority to the parent applications, “for the same reasons that said claims constitute new matter.” Applicants submit that withdrawal of the new matter rejection should also result in the granting of the claimed priority. It is noted that the instant application is one of a series of continuations (not continuations-in-part) that include all of the parent applications to which priority is claimed. Therefore, the disclosure of the instant application is identical to that of the parent applications and, if written description support is found for the amended claims in the instant application, then priority to the parent applications should be granted, based on the same written description support.

Rejection of Claims Under 35 USC 102(b)

The claims were rejected under 35 USC 102(b) as anticipated by Leung et al. (US Patent 5,789, 554). Applicants respectfully traverse.

Applicants note that the ‘554 patent issued from USSN 08/690,102, which was the grand-parent of the instant application and to which priority should properly be granted, as discussed above. Further, if Leung et al. discloses each and every element of the presently claimed invention, as required to support a rejection under 35 USC 102, then priority to the application of Leung et al. should properly be granted, as that application would then support the instant claims.

Rejection of Claims Under 35 USC 103

The claims were rejected under 35 USC 103(a) as obvious over Goldenberg et al., in view of Morrison et al., Cabilly et al, Boss et al., Orlandi et al. and Huston et al. (US Patent 5,258,498). The Action states that, "Goldenberg et al. teach the murine LL2 monoclonal antibody and hybridoma producing said antibody." The Action asserts that it would have been obvious to apply the methods of Morrison et al, concerning chimeric antibody production, to the monoclonal antibody LL2 disclosed in Goldenberg to produce chimeric or humanized LL2 antibodies or fragments.

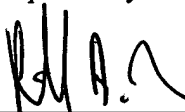
Applicants respectfully traverse. There is no disclosure in Goldenberg et al. of the CDR sequences used to construct the claimed chimeric or humanized LL2 antibodies. Nor was the LL2 antibody publicly available as of the instant application's filing date. Thus, without either the CDR sequences used or a source of the mouse LL2 mAb, the skilled artisan would have had no way to construct the claimed humanized or chimeric LL2 antibodies or fragments thereof, which depend on the incorporation of LL2 CDR sequence. Attached herewith is a Declaration of Goldenberg, of record in this application, stating that the expression vectors encoding the hLL2 light and heavy chain variable sequences were not deposited until October 8, 2002, well after the December 22, 2000, filing date of the instant application. As discussed in the attached Declaration of Hansen, prior to 2002, the cloned vectors were maintained in the Department of Cellular and Molecular Biology at Immunomedics, Inc., where they were not publicly available.

Since neither the CDR sequences nor the LL2 mAb were publicly available as of the instant filing date, let alone the instant priority date, the skilled artisan would have had no reasonable expectation of success in making and using the claimed invention. Reconsideration and withdrawal of the rejections are respectfully requested.

Conclusion

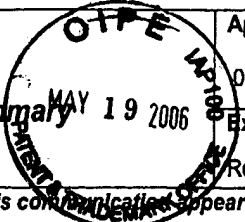
For the reasons stated above, Applicant submits that the claims as amended are in condition for allowance and requests withdrawal of the rejections.

Respectfully submitted,



Dated: May 17, 2006

Richard A. Nakashima
Reg. No. 42,023

Office Action Summary 	Application No. 09/741,843	Applicant(s) LEUNG ET AL.	
	Examiner Ron Schwadron, Ph.D.	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 95-149 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 95-149 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: ____ |

1. This application contains claims directed to the following patentably distinct species of the claimed invention.

The various different nucleic acids encoding a particular antibody. For example, the nucleic acid encoding the antibody of SEQ. ID. NO:2 and 4, or the nucleic acid encoding the antibody of claim 111, etc).

These are different antibodies with different sequences.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or

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Art Unit: 1644

relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644


RONALD D. SCHWADRON

PRIMARY EXAMINER

GROUP 1600



1111-11

Atty. Dkt. No. 018733-0996

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Shui-on LEUNG et al.

Title: IMMUNOCONJUGATES AND HUMANIZED ANTIBODIES SPECIFIC FOR B-CELL LYMPHOMA AND LEUKEMIA CELLS

Appl. No.: 09/741,843

Filing Date: 12/22/2000

Examiner: Ronald B. Schwadron

Art Unit: 1644

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop NON-FEE AMENDMENT
Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

In a timely response to the restriction requirement set forth in the Office Action mailed December 18, 2003 Applicant hereby provisionally elects claims directed to a polynucleotide sequence encoding an antibody that contains one or more CDRs from SEQ ID NOS: 2 and/or 4 (amino acid sequences of the variable light and heavy chain murine LL2 monoclonal antibody) or components of these antibodies, such as individual CDRs, light chain variable regions or heavy chain variable regions containing these CDRs. Applicants therefore elect claims 95-110, 113-117, 120, 121, and 124-133, 136-143, and 146-149 for examination, with traverse. These elected claims are directed to polynucleotide sequences that encode antibody or antibody components containing one or more of these CDRs.

The Examiner has required restriction between claims to polynucleotides to different antibodies. Applicants submit that the claims directed to polynucleotides encoding entire murine variable light and heavy chain regions as claimed in claims 118, 119, 134, 135, 144 and 145 also encode the same CDRs as in the elected claims and should be examined with the elected claims. Applicants respectfully request reconsideration of the Examiner's position.

In regard to the election of species, the Examiner has indicated that upon the allowance of a generic claim, additional species which contain the limitations of the generic claims would be allowable. Accordingly, applicant requests full examination of the generic claims once the elected species is found allowable.

Reconsideration of the restriction requirement is therefore respectfully requested as indicated above. Applicants, of course, reserve the right to file one or more divisional applications covering the subject matter of the non-elected claims and species. Examination on the merits is kindly requested.

Respectfully submitted,

Date January 20, 2004

FOLEY & LARDNER

Customer Number: 22428

Telephone: (202) 672-5569

Facsimile: (202) 672-5399

By Stephen B. Maebius
for Stephen B. Maebius Reg. No. 34,485
Attorney for Applicant
Registration No. 35,264

Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Attorney Docket No. 18733/996

In re patent application of

Shui-on LEUNG et al.

Serial No. 09/741,843

Filed: December 22, 2000

Group Art Unit: 1644

Examiner: R. Schwadron

For: IMMUNOCONJUGATES AND HUMANIZED ANTIBODIES SPECIFIC
FOR B-CELL LYMPHOMA AND LEUKEMIA CELLS

DECLARATION UNDER 35 U.S.C. § 1.132

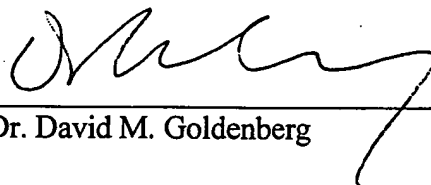
1. The undersigned declares that he, as Chairman of the Board and founder of Immunomedics, Inc., the assignee of the above-identified application, directed the deposit of two expression vectors, hLL2pKh containing the hLL2 light chain variable region, designated as ATCC No. PTA-4747, and hLL2pG1g, containing the hLL2 heavy chain variable region, designated as ATCC No. PTA-4748, at the American Type Culture Collection, 10801 University Blvd. Manassas, VA 20110-2209, a Budapest Treaty recognized depository which affords permanence of the deposit, on October 8, 2002. A copy of the deposit receipt is enclosed for convenience.

2. I state that the deposited expression vectors are the expression vectors which are specifically identified in this application as filed. I further provide that during the pendency of the patent application access to the deposited expression vectors will be allowed to those persons properly designated by the Commissioner of Patents and Trademarks; that the deposited expression vectors will be replaced should the cells containing them die or be destroyed during the enforceable life of any patent issued out of this patent application, for five years after the last request for a sample of the deposited expression vectors or for thirty years, whichever is longer; that upon issuance of a patent, applicants will irrevocably remove all restrictions to access to the expression vectors for the duration of the deposit; and that maintenance charges for the duration of the deposit will be paid.

3. All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true; further, these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or

imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

January 10, 2003
Date


Dr. David M. Goldenberg

ATCC

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-365-2745

**BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE**

INTERNATIONAL FORM

**RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.**

To: (Name and Address of Depositor or Attorney)

Immunomedics, Inc.
Attn: Timothy Qu
300 American Road
Morris Plains, NJ 07950

Deposited on Behalf of: Immunomedics, Inc.

Identification Reference by Depositor:

Plasmid vector: hLL2pKh
Plasmid vector: hLL2pG1g

Patent Deposit Designation

PTA-4747
PTA-4748

The deposits were accompanied by: a scientific description a proposed taxonomic description indicated above. The deposits were received October 8, 2002 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested October 28, 2002. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

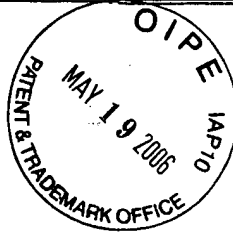
Signature of person having authority to represent ATCC:

Marie Harris
Marie Harris, Patent Specialist, ATCC Patent Depository

Date: November 6, 2002

cc: Stephen B. Maebius, Esq.
(Ref: Docket or Case No.: 018733/0996)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Attorney Docket No. 18733/996

In re patent application of

Shui-on LEUNG et al.

Serial No. 09/741,843

Filed: December 22, 2000

Group Art Unit: 1644

Examiner: R. Schwadron

For: IMMUNOCONJUGATES AND HUMANIZED ANTIBODIES SPECIFIC
FOR B-CELL LYMPHOMA AND LEUKEMIA CELLS

DECLARATION UNDER 35 U.S.C. § 1.132

I, Hans J. Hansen, state and declare that:

1. I hold the position of Emeritis Vice President, Research & Development & Intellectual Property at Immunomedics, Inc., Morris Plains, New Jersey, the assignee of the above-identified application and I also am a named inventor of the above-identified application.
2. I confirm that the two expression vectors, hLL2pKh containing the hLL2 light chain variable region, and hLL2pG1g, containing the hLL2 heavy chain variable region, were maintained in the Department of Cellular and Molecular Biology at Immunomedics, Inc., under the direct supervision of Dr. Shui-on Leung, the other named inventor of the above-identified application, and then under the direct supervision of Dr. Timothy Qu, prior to the filing date of the original parent application, U.S. Serial No. 08/289,576 filed on August 12, 1994, until they were deposited by Dr. Qu at the American Type Culture Collection, 10801 University Blvd. Manassas, VA 20110-2209, a Budapest Treaty recognized depository which affords permanence of the deposit, on October 8, 2002 and have been given the ATCC Nos. PTA-4747 for hLL2pKh and PTA-4748 for hLL2pG1g. This laboratory department within Immunomedics, Inc. was ultimately under my supervision, and Drs. Leung and Qu reported to me on the maintenance of these vectors.
3. I confirm that the hLL2pKh and hLL2pG1g that were deposited at the American Type Culture Collection are the same hLL2pKh and hLL2pG1g that are identified as pKh and pG1g, respectively, in the specification of the above-identified application as filed.

Declaration of Dr. Hans. J. Hansen

4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

January 7, 2003
Date

Hans J. Hansen
Hans J. Hansen, Ph.D.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,843	12/22/2000	Shui-on Leung	018733-0996	9659

22,428 7590 12/18/2003

FDLEY AND LARDNER

SUITE 500

3000 K STREET NW

WASHINGTON, DC 20007

EXAMINER

SCHWADRON, RONALD B

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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